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Regulatory Directive DIR2010-04

Guidelines for Reliance on Proprietary Data Under the Pest Control Products Regulations

(publié aussi en français)

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1.0 Introduction

The data protection provisions published June 23, 2010 by the *Regulations Amending the Pest Control Products Regulations – SOR/2010 - 0119* (PCPR) establish a legal framework by which an applicant or registrant may rely on data provided by other registrants. Prior to these amendments to the PCPR, data required for the registration of pest control products was protected by way of policies such as the 2007 Protection of Proprietary Interests in Pesticide Data and the 1987 Product Specific Registration II (PSRII). These policies were voluntary in nature and were not enforceable. The new PCPR provisions are legally enforceable and must be respected by all the parties involved.

These new regulations were introduced to allow for fair protection of proprietary interests in data in order to encourage introduction of new and reduced-risk pest control products, while at the same time providing a predictable and timely process for the introduction of competing generic products to the Canadian market. The addition of an incentive for registrants to register Minor Uses through the extension of the data protection period is also expected to result in the availability of a greater number of products for users.

These guidelines explain how Health Canada's Pest Management Regulatory Agency (PMRA) intends to administer these new regulations in the context of an application to register or amend a registration and what is expected of each party. A separate guideline on the administration of the regulations in the context of re-evaluations and special reviews will be published. It should be noted that since this is a new process, the PMRA may have to modify the approaches described in this document in order to accommodate unforeseen scenarios. Applicants and registrants are encouraged to communicate with the PMRA for any questions they may have on the new Regulations. The approach outlined in this document will be reassessed once sufficient experience with the new process has been gained.

1.1 Scope

This guideline applies to any case where an applicant, or a registrant, wishes to rely on studies provided by another registrant and used to support a regulatory decision. This includes data used for the registration of technical grade of active ingredients (TGAI), manufacturing concentrates (MA), and end-use products (EP).

This guideline does not apply to the following cases:

- Applicants are relying on their own data
- A letter of access (LOA) to all relevant data has been provided
- The applicant has previously secured access to the data through the previous PSRII policy
- The applicant is relying on test data from the registrant who is providing the pest control product used in the manufacture of the applicant's product (Section 17.4 PCPR). A letter of confirmation of source (LOC) would be required in this case. However, an amendment to replace or add a source from another registrant could trigger the need for compensation.

2.0 Reliance on data for registration or amendment to a registration[1]

2.1 Reliance on data during the exclusive use period

An exclusive use period is granted to data identified under section 17.5 of the PCPR. During the exclusive use period, which may be from 10 to 15 years, access to data may only be obtained through voluntary negotiation with the registrant. In such a case, the applicant would have to provide a LOA from the registrant with its application. A LOC from the registrant may also allow the applicant to rely on the registrant's data.

The Agency will consider applications to register new products based on the registrant data in the last 18 months of the exclusive period[2]. During this period, the Agency will conduct an equivalency assessment and identify any compensable data on which the applicant may need to rely. The intent is to enable parties to initiate and complete the negotiation process in time for the registration to proceed once the exclusivity period has lapsed.

2.2 Reliance on compensable data

Compensable data as defined in section 17.1 of the PCPR may only be relied upon under certain conditions. In order to rely on compensable data, companies are required to provide a LOA, a relevant LOC meeting the criteria identified in section 17.4 of the PCPR, or to demonstrate that conditions highlighted in section 17.94(2) of the PCPR exists. A LOA may be obtained through voluntary negotiation between the parties outside of, or within, the framework provided by the PCPR.

2.2.1 Cite-all and selective approaches for reliance on compensable data

2.2.1.1 Cite-all approach

This approach consists of citing all studies from the database of the relevant product(s).

2.2.1.2 Selective approach

The selective approach entails relying on only a subset of the data in a precedent database. It should be noted that many studies apply to the entire use pattern of a product in which case such studies would have to be relied upon regardless of the applicant's product proposed use pattern.

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1 It should be noted that the ability to rely on data does not mean that the data can be released to the applicant. Confidential test data may only be consulted under the circumstances provided for in the Act.

2 Applications where a LOA or LOC was provided may begin prior to the last 18 months of the exclusive period.

Applicants who chose the cite-all approach may switch to a selective approach and withdraw some proposed uses upon reviewing the protected data list. It is important that such a request be made prior to sending the Ministerial Agreement to the registrant(s). The Agency would then revise the list accordingly. However, this will result in delays to the registration process as further assessments and consultations with the registrants will be required.

2.3 Reliance on unprotected data

Unprotected data refers to data for which the protection period has lapsed or data that is not eligible for protection. Unprotected data may be relied upon by any party without compensation or LOA.

2.4 Multiple registrants of equivalent products

For TGAIs, there may be more than one registrant of a particular active ingredient. Not all registrants may have contributed equally to the overall database. For that reason, a LOA from a single registrant may not be sufficient. The applicant may still have to rely on relevant studies missing from the database for which a LOA was provided.

For EPS, the PMRA will look at the submission history of cited precedent(s) and of any relevant data supporting the precedent(s).

3.0 Application requirements:

3.1 General requirements

An application to register a new product or amend a registered product based on an existing database will require the following:

- Cover letter
- Application form
- Fee Form and appropriate fees
- Statement of Product Specification Form (SPSF)
- Text label
- e-index in XML format
- Copy of a letter informing current registrant(s) of the applicant's intention to register a new product based on previously submitted data
- Copy of LOA(s) or Letters confirming Task Force membership, where applicable

3.1.1 Cover letter

The letter must contain the following:

- The purpose of the application.
- The intent to rely on another registrant's data.

- In the case of EP, valid precedent(s) must be identified as per section 4.1 criteria on selecting a valid precedent.
- In the case where the applicant has rights to rely on data through membership in a task force or with a LOA, a statement must be included in the cover letter and the actual LOA or a letter confirming membership must be provided.
- If data was included, an explanation must be provided. For example, if the applicant has anticipated that the Agency would require it or if the applicant only wants to rely on part of a precedent data set.

The applicant should also indicate whether a cite-all or selective approach should be taken.

3.1.2 Application form

Applications to register a new source of a TGAI must indicate "Category B Other" on the application form.

For EPs and MAs, the most relevant Category should be used and the precedent(s) identified in the appropriate box.

3.1.3 Fees

The application fees will be assessed as outlined in the Guidance Document on Pest Control Products Cost Recovery Fees (Dated April 16, 1997).

3.1.4 Statement of product specification form

For TGAI, a SPSF must be submitted for every site of manufacture. For EP and MA, a SPSF for each of the proposed formulations is required.

3.1.5 Label

The label of the proposed product should conform to the label of the cited precedent(s) and include, where applicable any change required as a result of re-evaluation. The use pattern will be limited to that of the precedent product(s) at the time of application or a subset of those uses.

3.1.6 E-index

The e-index is an electronic index in XML format that describes each document submitted. Please refer to Regulatory Directive DIR2006-05, Requirements for Submitting Data Index, Documents and Forms.

3.1.7 Letter to current registrants

To allow the registrant(s) to initiate the process of identifying their protected data and to allow both parties to prepare for the upcoming negotiation, the Agency is asking that applicants contact all current registrants of the TGAIs or of the cited precedent(s) for MA and EP prior to applying for registration. The letter should be based on the template found in Appendix I. Applicants choosing a selective approach should add a list of the proposed uses to the letter. Failure to submit such letter may result in the application being put on Hold to allow the applicant to send a letter to the registrant(s).

3.1.8 Copy of LOA or letter confirming task force membership

In cases where an applicant already has access to protected data, a LOA from the data submitter must accompany the application package (see section 5.5 on Letter of Access). Similarly, if the applicant is a member of a task force, a proof of membership must be provided.

3.2 Simultaneous applications

In many cases, the applicant may wish to apply simultaneously for registration of a new source of TGAI and a similar EP or MA containing this TGAI. In such a case, a separate application will be required for each TGAI, EP, or MA. The Agency will attempt to synchronize these applications so that they reach the negotiation step at the same time.

3.3 Application to register a new source of a technical grade of active ingredient

In addition to the requirements identified in section 3.1, applications to register a new source of a TGAI will also require chemistry data (Part 2: Chemistry requirements for the registration of a technical grade of active ingredient or an integrated system product).

3.4 Application to register or amend an end-use product or manufacturing concentrate

In addition to the requirements identified in section 3.1, applications to register or amend an EP or MA may also require bridging data and/or scientific rationale to support the establishment of equivalency.

3.5 Application to add a new use site category to an already registered TGAI

If the application proposes to add a new use site category to a currently registered source of TGAI, the applicant will have to gain access to all compensable data supporting the additional USC. The applicant may also have to gain access to compensable data that was relied upon during re-evaluation or special review[3]. The application letter will have to identify the data to which the applicant already has access and provide the LOA from the owner of the data. The existing chemistry data may be re-assessed during initial review and, if gaps are identified, new

[3] Data on hand used for re-evaluation purpose does not require compensation from registrants until used in the context of a registration or an amendment to a registration.

data may be requested. If the new assessment reveals that the equivalency to the cited TGAI is no longer valid, the application may be withdrawn.

3.6 Application relying on data from a historical product or use

Historical products are products which are no longer registered. Historical uses are uses that have been removed from the label of a registered product. Applicants may still rely on the data which support historical products or uses. Such applications will typically require a full review of the precedent and will be handled on a case by case basis.

4.0 Registration process

4.1 Verification and screening

Upon receipt of the application, the package will be verified for completeness and screened for format, data and fee requirements. In the case where significant deficiencies are identified, the application will be put on Hold. If there is no response or if the response is incomplete or inadequate, the application will be withdrawn.

For end use products, the validity of the precedent will be confirmed at screening based on the following criteria:

- The precedent product must be a pest control product that is or has been registered in Canada
- The precedent must be substantially similar to the proposed product. Differences may be acceptable if they are deemed to have no adverse implications on the product's risk, residues or efficacy.
- The cited precedent cannot have been registered as a similar product or identical product. In this case the PMRA will identify the initial product to the applicant in order to initiate the data compensation process.
- A maximum of two precedents may be cited to support an application; in such cases, the applicant must explain in the cover letter how each precedent supports the application.
- It should be noted that the Agency will verify whether the selected precedents are actually copies of another product. The original precedent will serve as a basis for an equivalency assessment and identification of protected data. It should be noted that the original precedent's registrant may also be different.
- For standard Category C application, an equivalency assessment and an analysis of the database of the precedent product will also be performed. If equivalency has been established and there is no data meeting the eligibility criteria outlined in the Regulations, the Agency will proceed with the registration.

4.1.1 Requests for identification of protected data

The following process will be used to identify protected data for applications other than standard Category C applications relying solely on unprotected data:

1. At screening, the PMRA will contact the registrant(s)[4] who submitted the data supporting the precedent product(s) or use(s) and provide a PMRA Data List[5] .
2. The registrant may submit references to any additional data not represented on the PMRA Data List within 30 days. The Registrant's Amended Data List[6] must be in the same form as the PMRA Data List. An explanation as to why the additional data should be considered as compensable should be provided as well as any documented evidence.
3. The PMRA will analyse the PMRA Data List, or the Registrant's Amended Data List and identify the compensable data.
4. The registrant will be provided with a Preliminary List of Compensable Data[7] and will have 15 days to appeal this list and to provide any additional comments or supporting documentation.
5. The PMRA will consider the comments provided and issue a List of Compensable Data[8] to the Registrant and Applicant. Once a List of Compensable Data is established for a product, the above process will serve to confirm its continued validity.

Should the registrant fail to reply to PMRA's requests within the given timelines, the Agency will consider that the registrant found the list provided to them to be accurate.

In cases where the selective approach is requested, the PMRA will create a different list identifying the studies which will need to be relied on for the applicant's requested uses. The registrant will then be provided with that list and with a description of the use pattern of the applicant's product. The applicant should not change the List of Compensable Data when sending the ministerial agreement to the registrant as this may jeopardize the registration of their product.

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4 The registrant will be responsible for identifying all protected data that was submitted to the PMRA in support of their product, including data provided by a third party

5 PMRA Data List: A listing of all data which the PMRA has attached to a registered pest control product, including studies which may no longer be protected

6 Registrant's Amended Data List: A listing of the data attached to a registered pest control product which the registrant claims is compensable

7 Preliminary List of Compensable data: The initial list of data which meet the compensable criteria outlined in the PCPR

8 List of Compensable Data: The list of compensable data for which access must be negotiated

4.3 Outstanding data requirements

Outstanding data requirements from conditional registration, the re-evaluation process, a special review, or an ongoing review may be identified within a separate list. Applicants may want to reach an agreement on those as well. However, compensation is not required for this data as it has not yet been relied upon for a regulatory decision. The applicant will however have to commit to provide any outstanding data, or alternatively a LOA, by a time specified by the PMRA. The renewal period of the applicant's product will be set accordingly.

4.4 Equivalency assessment

The PMRA will establish whether the applicant's product and the cited precedent are equivalent. If necessary for this determination, the PMRA may request that additional data or a scientific rationale be submitted by the applicant. In such a case the application will be put on hold for 90 days to allow for the submission of this information. Lack of, or an inadequate response within 90 days will result in the application being withdrawn. Data other than chemistry data will be reviewed according to the Management of Submission Policy timelines. Should it be determined that the applicant's product is not equivalent to the cited precedent, the submission will be withdrawn. The applicant will have to re-apply with the required data in order to register their product.

The equivalence between two sources of conventional TGAI will be based on following criteria:

- The active ingredient must be identical.
- The manufacturing process should be similar.
- The guarantee of the active ingredient in the new TGAI must be ± 5% relative to the guarantee in the cited TGAI (e.g. for a registered TGAI having a guarantee of 80%, the acceptable guarantee range for the proposed TGAI would be 76% to 84%).
- The total weight of non-identical impurities must be below 5%.
- The micro-contaminants levels must be equal to or lower than in the currently registered source.
- The chemistry data (part 2) must be complete.

The equivalence between two sources EPs or MAs will be based on criteria identified as follows:

- the active ingredient(s) must be the same concentration (i.e., within the standard certified limits);
- the formulation type must be the same;
- the chemical and physical properties are similar;
- the formulant(s) must be equivalent and at equivalent concentrations with the same functionality.

The Agency recognizes that some products not meeting these criteria may represent a similar or reduced risk to human health or to the environment. Consequently, products that do not meet these criteria may still qualify for registration but may require further science review to assess the significance of the differences on the product's risk, efficacy and residues. This may result in longer review timelines.

4.5 Timelines

For an application using the cite-all approach, the PMRA intends to verify, screen, review, and establish the list within 120 days provided that there are no deficiencies. Products for which a re-evaluation was recently completed and for which a compensable data list was never established may take additional time.

For an application using the selective approach, the Agency intends to verify, screen, review, and establish the list within 195 days provided that there are no deficiencies.

4.6 Label

The proposed label will be reviewed concurrently with the equivalency assessment. Any required correction will be sent to the applicant with the list of compensable data. The applicant must provide a corrected bilingual version with the LOA (see section 5.5). Upon receipt, the PMRA will verify that the required amendments have been made and that the translation is accurate.

5.0 Negotiation and binding arbitration

5.1 Ministerial Agreement

The PMRA will send a letter to both the registrant and the applicant to indicate that equivalency has been established and to provide the list of protected data. In order to initiate the negotiation process under the PCPR, the applicant must send to the registrant(s) a signed copy of the Ministerial Agreement by a means that provides proof of delivery. The Ministerial Agreement can be found on Health Canada's website.

5.2 Negotiation

Applicant and registrant(s) will have 120 days to complete negotiations as per the PCPR unless the parties agree otherwise. The PMRA will not be a party to the negotiation process. The result could be a negotiated agreement and a LOA, or a request to go to binding arbitration. The applicant may also decide to withdraw from the process.

5.3 Early registration

The PCPR allow for an early registration provided certain conditions are met. In order to consider registration (see section 6.0), the applicant must demonstrate that these conditions have been met or that the circumstances described in section 17.92 of the PCPR exists.

5.4 Binding arbitration

In cases where an agreement could not be obtained during the 120-day mandatory negotiation, the applicant can request binding arbitration as per the PCPR. The PMRA will not be a party to the arbitration process. The result could be a negotiated settlement or an arbitral award both of which leading to a LOA to the data being relied upon. The applicant may also decide to withdraw the application.

5.5 Letter of access

Once a negotiated settlement has been reached or an arbitral award has been rendered, the registrant must provide to the applicant a LOA allowing the applicant to rely on the data identified in Appendix A of the ministerial agreement as listed by the Minister. Section 17.94(2) of the PCPR may otherwise apply. The LOA should be prepared based on the template in Appendix II. A LOA must have no limitation other than a limitation on the period of validity where payments are still outstanding as per the settlement or award. The PMRA will not proceed with the registration until an acceptable letter is submitted. For example, limitations on the uses of data to which the applicant has gained access would not be acceptable. This does not prevent applicants and registrants to make other arrangements but the PMRA will not enforce a business agreement on behalf of the companies. It will be up to the parties to monitor and enforce compliance of these agreements.

6.0 Registration

The applicant must submit the LOA once it has been obtained, or submit the information required under section 17.93 of the PCPR when the applicant has met the conditions for an early registration.

The Agency will check whether there are any outstanding data. Should that be the case, the applicant will be asked to commit to provide the data or gain access to it within a specified time frame. Once the LOA from the registrant, the final labels and the letter of commitment for the outstanding data (if applicable) have been received, the Agency will proceed within 45 days with the registration of the pest control product.

When a negotiated settlement is reached or an arbitral award is issued, if the registrant has not provided a LOA, the Applicant may deliver to the PMRA proof that the condition of the settlement or award where met. The PMRA will consider the information provided and grant registration if all conditions are met as per section 17.94 of the PCPR.

6.1 Renewal

In cases where the compensation was paid in full prior to registration, products will be registered for a period of up to five years after which the registrant will have to apply for renewal. Other factors, such as the need to submit outstanding data or to secure a LOA to such data, will have an impact on the renewal period.

In cases where the payment or part of it is due after registration has been granted (e.g., schedule of payment), the registration will be granted for a period determined by considering the schedule of payment and the renewal process. Under such circumstances, the registrant who is making the payment will have to provide at renewal a LOA from the registrant being compensated. Once all payments are met, the last LOA will be considered valid and without time limitations.

7.0 Extension of exclusive protection

The minor use incentive provisions of the PCPR outline how and when registrants may ask for an extension to the exclusive protection status of their proprietary databases. Data that qualifies for exclusive protection status will normally receive ten years of exclusive protection from the date of first registration. The exclusive protection provided to the original data set will be extended by one year for each three eligible minor use crops added to a label, up to a maximum of five additional years of exclusive data protection. Eligible minor uses that were registered as part of the original application will also be considered.

7.1 Eligibility criteria

7.1.1 Expression of government and user support

To qualify towards an extension of exclusive data protection, a minor use requires evidence of support from users and from a federal or provincial agricultural authority. The Minor Use Priority List, prepared by Agriculture and Agri-Food Canada in consultation with provincial governments and grower groups, as well as provincial letters of support for User-Requested Minor Use Label Expansion Submissions (URMULES), will be sufficient to meet this requirement. An active ingredient may not need to be on the list as long as it addresses a crop/pest combination identified in the list. Any other evidence will be considered on a case-by-case basis.

7.1.2 Qualifying data

As per the PCPR, only crop/pest combinations that are supported by crop residue or dislodgeable foliar residue data will qualify towards an extension of exclusive data protection. Only the crops tested will be considered for the purposes of determining the number of eligible minor uses. In the case of crop groups, the maximum number of eligible minor uses in the crop group will be the number of representative crops.

7.1.3 Timing of minor use data submission

Only minor uses for which the data was submitted with the first application or within seven years after the first registration of a TGAI will qualify towards an extension of exclusive protection status (see section 17.5(3) of the PCPR).

7.2 Process to request extended data exclusivity protection

Extension of the exclusive protection status of a pesticide database following the registration of eligible minor uses is not automatic. Registrants must submit a request to PMRA to extend the exclusive protection status no later than eight years[9] after the first registration of a TGAI. Registrants should submit only one letter requesting an extension of the exclusive protection for each TGAI. The letter should provide the following information:

- Name and pest control product registration number of the product(s) for which an extension is sought.
- Submission number of the application(s) which resulted in the registration of the minor uses and the application date.
- The minor uses added, the representative crop for the group if applicable[10], and the crops with which the eligible data was generated.
- The total number of years of extension being sought.
- A proof of support by users and provincial or federal agricultural authority.

7.3 Decision

Once a request has been made to extend the exclusive protection period, the Agency will verify within 6 months the information provided and decide on the acceptability of the request. The Agency will communicate its conclusion to the registrant who will have 15 days to appeal. Once a final decision has been reached, the Agency intends to publish the information on its website.

7.4 Revocation

An extension of exclusive data protection will be reduced if, during the period of exclusive data protection, an applicable minor use is withdrawn and the remaining minor uses are not sufficient to support the extension. The Agency intends to publish the information on its website.

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9 The Transitional provisions of the PCPR allow for a different delay under some circumstances.

10 The registrant should identify whether the crop groups have changed since their minor use application.

Appendix I Template Letter From Applicant to the Current Registrant(s)

[COMPANY LETTERHEAD]

Date

Name of Registrant
Address of Registrant

Dear :

Re: [Name of product and Registration No.]

Please be advised that [NAME OF APPLICANT] has submitted to Health Canada's Pest Management Regulatory Agency (PMRA) an application to *(register or amend a registration)* that may be relying on data submitted by [NAME OF REGISTRANT]. According to the Pest Control Products Regulations, the PMRA must establish a list of compensable data relevant to this application. You may be requested by PMRA to identify compensable data relevant to this application. Therefore, [NAME OF REGISTRANT] should expect to be contacted shortly by the PMRA with a request to identify data that [NAME OF REGISTRANT] considers to be compensable data as per the Pest Control Product Regulations. [NAME OF REGISTRANT] has 30 days to do so. Please prepare accordingly.

Please also note that [NAME OF APPLICANT] will be contacting you shortly to initiate discussion about the upcoming negotiation process.

Thank you for your cooperation in this matter.

[Applicant's signature]
[Printed signatory name and contact information]

Appendix II Letter of Access

[COMPANY LETTERHEAD]

Date

Chief Registrar
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, ON K1A 0K9

Subject: Letter of access to [NAME OF APPLICANT]

This is to inform you that [NAME OF REGISTRANT] is granting to [NAME OF APPLICANT] the right to rely on [NAME OF REGISTRANT]'s protected data identified in the Pest Management Regulatory Agency's letter of [DATE].

Yours truly,

[Registrant's signature]
[Printed signatory name and contact information]